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TITLE: Post-Traumatic Headache and Psychological Health: Mindfulness Training for Mild Traumatic Brain Injury

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## Introduction

Traumatic brain injury has been coined the signature injury of OIF/OEF, with posttraumatic headache being a cardinal symptom found to be as high as 36% of soldiers with MTBI. Combat-related headaches are undertreated, associated with high sick calls, missed days, negative psychological/mood states, and impair overall quality of life. Comorbid anxiety, depression, PTSD and other psychological, psychosocial, and health stressors portend poorer TBI/headache outcomes, supporting the need for integrative health care. Development, evaluation, and integration of a specialized posttraumatic headache treatment program into a comprehensive TBI rehabilitation effort is critical to restoration of function, health, and quality of life of our soldiers. This project addresses multiple FY09 TBI/PH topic areas by validating an evidence-based, mind-body approach for prevention and treatment of post-TBI headache, stress, and associated psychological health issues in order to restore function, enhance well being, prevent post-TBI headache chronicification, develop psychological resilience, and promote long-standing health benefits. The focus of this project is on evaluation of mindfulness based stress reduction as one, potentially critical component of a comprehensive rehabilitative effort for this group of MTBI patients.

## Body

This project marks the collaboration between the University of North Carolina at Chapel Hill (UNC), Womack Army Medical Center (WAMC), and the Carolina Headache Institute (CHI). During these first 11 months, we accomplished the majority of the goals proposed in the Statement of Work. Specifically, we developed and finalized the protocol (e.g., consent forms, study measures, recruitment materials), data entry and tracking system, the mindfulness meditation intervention, headache education intervention, mindfulness study manual, and the randomization protocol. By the end of the fourth quarter, we anticipate final approvals from the WAMC/UNC IRBs. Currently, we have conditional approvals and are making the requested changes. We purchased and set-up essential equipment (neurocognitive/psychological testing materials, laptop). We established a UNC/WAMC collaborative research meeting structure, and recruited/trained key personnel, including mindfulness instructors and the UNC research assistant.

Our projected timeline was delayed on IRB approvals, subject screening/recruitment, and establishment of the Data Safety Monitoring Board (DSMB). We anticipated final IRB approvals within the first 6 months. We consequently projected that initial screening and recruitment of potential participants would begin by the end of the 4<sup>th</sup> quarter. Multiple WAMC personnel changes delayed IRB approvals. The new WAMC TBI director (Major Steve Lewis) requested multiple meetings in order to fully understand and approve the study. The WAMC local PI, Dr. Stacy Ketchman, was our primary collaborator with regard to IRB document preparation. After she left WAMC, time was devoted to the identification of the new local PI, Dr. Keisha O'Garo. Because Dr. O'Garo was new to WAMC, she needed time to orient herself to TBI Center operations/facilities and the WAMC IRB paperwork/application process. Regarding the DSMB, we are in the process of identifying board members.

## Key Research Accomplishments

- Identified WAMC-PI
- Finalized study protocol, ICF and recruitment materials.
- Conditional IRB approval from WAMC.
- Established standing inter-institutional research meetings
- Created database for secure data entry, storage and analysis via Redcap

## Reportable Outcomes

Considering examples provided in instructions, we consider this not applicable to our project at this time.

## Conclusion

We have accomplished the majority of the tasks outlined in the SOW. With final approval from the WAMC-UNC IRBs, we can progress toward HRPO approval and recruitment soon thereafter. We have established good inter-institutional communication and a regular research meeting structure. These achievements offer a good foundation for the proposed research project.

## **References**

Not applicable

## **Appendices**

Not applicable